510(k) SUMMARY

MAY 2 4 2013

Circadiance LLC SleepWeaver Anew Full Face Soft Cloth PAP Mask

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Date Prepared: February 18 2013

Name of Device and Name/Address of Sponsor

SleepWeaver Anew Full Face Soft Cloth PAP Mask

Common or Usual Name

Full Face PAP Mask

Classification Name

BZD – ventilator, non-continuous (respirator); 21 CFR 868.5905

Predicate Devices

SleepWeaver élan Nasal CPAP Mask
Circadiance, LLC
Common/Usual Name: Nasal CPAP Mask
Classification: 21 CFR 868.5905
Product Code: BZD
Panel: Anesthiesiology

Mirage Quattro
ResMED, Ltd.
Common/Usual Name: Full Face PAP Mask
Classification: 21 CFR 868.5905
Product Code: BZD
Panel: Anesthiesiology

Intended Use / Indications for Use

The SleepWeaver Anew Full Face Soft Cloth PAP Mask is intended to provide an interface for Positive Airway Pressure (PAP) therapy. This mask is intended for single-patient reuse in the home and in the hospital/institutional environment. This mask is to be used on patients greater than 66 lbs (30 kg).

Technological Characteristics

The **SleepWeaver Anew Full Face Soft Cloth PAP Mask** consists of **a cloth cushion, headgear, and a 90° elbow swivel connector with anti-asphyxia valve.**

The optional SleepWeaver FeatherWeight tube may be used with this mask, but it remains outside the scope of this submission as it has been previously cleared by its inclusion in K120757.

Performance Data

Performance testing for the SleepWeaver Anew Full Face Soft Cloth PAP Mask included the following tests or evaluations:

- Material evaluation;
- Product performance testing;
  - *Physical Dead Space;*
  - *Anti-Asphyxia Resistance;*
  - *Anti-Asphyxia Operation;*
  - *Pressure Drop;*
  - *Carbon Dioxide Washout; and*
  - *Leak Rate.*
- Connector performance testing;
- Product usability evaluation;
- Biocompatibility;
  - *Patient Contract Duration: Permanent*
  - *Gas Pathway (External Communicating) Components: 90° swivel with anti-asphyxia valve, mask body material, nasal interface, and internal surface of the oral interface. The materials in these components have been used in legally marketed devices. Biocompatibility requirements met.*
  - *Surface Contact (Skin) Components: Headgear / mask wings, external surface of the oral interface. The headgear material has been used in legally marketed devices. The material used for the external surface of the oral interface represents a material not previously used in a legally marketed device and was, subsequently, subjected to Cytotoxicity, Sensitization, and Irritation testing according to the guidelines set by ISO 10993-1 and the FDA G95-1 memorandum. Biocompatibility requirements met.*
- Reliability;
- Packaging;
- Accessory interfacing;
- Storage testing;
- Labeling review; and

- Design analysis.

In all instances, the SleepWeaver Anew Full Face Soft Cloth PAP Mask functioned as intended and results of each test observed were as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 24, 2013

Mr. David Groll
Chief Executive Officer
Circadiance, LLC
1060 Corporate Lane
Export, PA 15632

Re: K130481
Trade/Device Name: SleepWeaver Anew Full Face Soft Cloth PAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: April 26, 2013
Received: May 6, 2013

Dear Mr. Groll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.05.23 14:59:36 -04'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130481

Device Name: SleepWeaver Anew Full Face Soft Cloth PAP Mask

Indications for Use:

The SleepWeaver Anew Full Face Soft Cloth PAP Mask is intended to provide an interface for Positive Airway Pressure (PAP) therapy. This mask is intended for single-patient reuse in the home and in the hospital/institutional environment. This mask is to be used on patients greater than 66 lbs (30 kg).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Amy K. Leevelle -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130481